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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/903,376	07/10/2001	Thomas J. Brennan	R-599	8327

26619 7590 02/28/2005

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1031 Bing Street
San Carlos, CA 94070

EXAMINER	
WILSON, MICHAEL C	
ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 02/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/903,376	BRENNAN, THOMAS J.	
	Examiner	Art Unit	
	Michael C. Wilson	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 September 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 32 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 32 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The Examiner of this application has changed. Please direct any further correspondence to Examiner Michael C. Wilson, Art Unit 1632.

Applicant's arguments filed 9-26-04 have been fully considered but they are not persuasive.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 101

Claim 32 is rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility for reasons of record.

Applicants argue the claimed invention has a well-established utility (pg 5, 2nd full ¶) because a person of ordinary skill would immediately appreciate why the knockout mice were useful to define the function and role of the disrupted gene. Applicants' argument is not persuasive.

MPEP 2701 II(A)(3) requires a "well-established utility" must be a utility that is specific, substantial and credible. While knockout mice were used for scientific research in the art at the time of filing, significant further research was required to determine the function of the gene using the mouse. In fact, the function of the gene may never be determined from the knockout mouse. Olsen (GABA in the Nervous System, 2000, pg 81-95) taught that "although gene targeting is often useful in delineating the contribution of a given gene product to phenotypic characteristics

observed, some gene knockouts lead to embryonic or perinatal lethality, and others lead to no apparent phenotype. This can arise from a lack of any role for the gene in question in regard to the trait studies or from compensation by other gene products. Analysis of the compensation can yield valuable clues to the genetic pathway" (pg 82, last 11 lines of col. 1). A mouse requiring significant further research to determine the function of the gene does not rise to the level of having a "well-established utility" (see utility guidelines, "[T]he following are examples of situations that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use and, therefore, do not define "substantial utilities": A. Basic research such as studying the properties of the claimed product itself or the mechanisms in which the material is involved"). In this case, the results of such further study may never reveal the function of the 5-HT-2B gene and least significant further study would have been required to use the knockout mice to determine the function of the 5-HT-2B gene.

Applicants point to an NIH report from 2004 (pg 5-6 of response) to establish the mice had "well-established" utility. Applicants' arguments are not persuasive.

The NIH report was not available until 2004 and cannot be used to establish what was "well-established" at the time of filing.

The NIH report suggests knockout mice may be models of disease; however, dead mice are not models of any disease.

Lastly, the references merely suggest using knockout mice to study the function of targeted genes, which does not rise to the level of a substantial utility according to the utility guidelines. The NIH report states knockout mice can be used to elucidate gene

function. The reference does not teach the mice will determine the function of the gene. Applicants have used the mice in expression analysis and phenotype analysis tests, but applicants have not determined the function of the gene. Simply using the mice for further research of the 5-HT-2B gene is not a specific or substantial utility. None of the references teach a specific or substantial utility for mice with a disruption in the 5-HT-2B gene as claimed.

Applicants argue the mice can be used as research tools. Applicants compare the mice claimed to gas chromatographs, screening assays and nucleotide sequencing methods. Applicants' arguments are not persuasive.

Regarding expression analysis, the specification does not teach what promoter is driving the LacZ reporter gene; therefore, it cannot be determined how expression of LacZ is relevant to determining anything about SEQ ID NO:1 (see Example 1, pg 51-53). If LacZ is operably linked to the 5-HT-2B promoter, the expression analysis revealed expression in the eye and testes of male mice. The expression analysis did not reveal the function of the gene.

Regarding applicants comparison to other research tools (pg 6, 1st full ¶ of response), gas chromatographs, screening assays and sequencing have specific, credible and substantial utilities. Gas chromatographs separate the chemical components of a compound and identify them. Screening assays have various functions, but may be used, for example, to determine the amount of protein expression in a population of cells. Sequencing methods provide the nucleotide sequence of a nucleic acid molecule. Unlike gas chromatographs, screening assays or sequencing

methods, the mice claims may not provide data that reveals the desired information: the function of the targeted gene. For example, applicants used the mice in expression analysis and behavioral analysis but did not determine the function of the 5-HT-2B gene. Further research would be required to determine the function of SEQ ID NO:1 using the expression analysis in Example 1. The utility guidelines state using a product for further research is not a "substantial" utility. In this case, the expression analysis does not even provide a clue as to the function of the 5-HT-2B gene. Therefore, using the mouse claimed as a research tool, specifically for expression analysis, does not provide any substantial utility.

Applicants cite Nebigil (PNAS, 2000, Vol. 97, Vol. 17, pg 9508-9513) of record who taught using 5-HT-2B knockout mice with embryonic lethality to determine the 5-HT-2B gene is required for heart development. Applicants conclude that the mouse claimed has utility. Applicants' argument is not persuasive. The embryonic lethality of the mice of applicants' invention was not disclosed in any of the provisional applications; therefore, the effective filing date of the claimed invention is the filing date of the instant application, 7-10-01. Nebigil did not teach how to determine the function of the 5-HT-2B gene in heart development. Therefore, using the mice claimed to determine the function of the 5-HT-2B gene in heart development is not a substantial utility because significant further research would be required to determine the effect of 5-HT-2B on heart development.

Applicants are reminded that In re Schoenwald, 22 USPQ2d 1671 (CA FC 1992) indicated that a product known in the art did not necessarily have

patentable utility. In this case, the mouse claimed might only provide a clue to a developmental process in which SEQ ID NO:1 is involved. This is not a specific utility because results from the tests may only indicate SEQ ID NO:1 is involved in heart development. The phenotype provides only a clue that SEQ ID NO:1 is generically involved in heart development influenced by numerous proteins.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

New claim 32 is rejected under 35 U.S.C. 102(a) as being anticipated by Nebigil (PNAS, 2000, Vol. 97, Vol. 17, pg 9508-9513) of record.

The embryonic lethal phenotype recited in new claim 32 was not disclosed in any of the provisional applications; therefore, the effective filing date of the new claim is the filing date of the instant application, 7-10-01.

Nebigil taught heterozygous 5-HT-2B knockout mice that when mated resulted in embryonic lethality of homozygous embryos.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

No claim is allowed.

Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached at the office on Monday, Tuesday, Thursday and Friday from 9:30 am to 6:00 pm at 571-272-0738.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

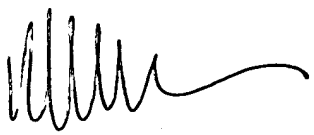
Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on 571-272-0735.

The official fax number for this Group is (571) 273-8300.

Michael C. Wilson



MICHAEL WILSON
PRIMARY EXAMINER